

Emily Brown Rosen
Organic Research Associates LLC
PO Box 5, Titusville NJ 08560
609-737-8630
ebrownrosen@gmail.com

Lynn Coody
Organic Agsystems Consulting
3460 McMillan St.
Eugene, OR 97405 USA
541-343-6795
LynnCoody@cs.com

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Mark Bradley, Associate Deputy Administrator
USDA-AMS-TMP-NOP
Room 4008-South Building
1400 Independence Avenue, SW
Washington, DC 20250-0020
via email: nop.livestock@usda.gov

Comments on Docket No. TM-06-06-PR

Dear Mark,

Organic Research Associates and Organic Agsystems Consulting are firms that work as advisors to organic farmers, accredited certification agencies, and other sustainable agriculture organizations. As owners and principals, we have a combined total of 38 years of experience in organic certification and technical issues related to standards setting and materials review. Thank you for the opportunity to comment on the proposed revisions to the NOP regulations. It is particularly important that the rules for transitioning dairy animals be clarified at this time to eliminate uncertainty in production practices. It would also be helpful if the final regulation clearly states the effective dates of implementation for the new measures, as well as the phase out date for previous regulations.

Revision of §205.236

We are in full support of the Organic Dairy Producers Alliance position (NODPA, MODPA, and WODPA), and the comments of certification agencies (PCO, NOFAs, OTCO, MOSA et. al.) regarding the needed changes in language regarding dairy herd replacement animals. It is critical that the new revision be written clearly to avoid a double standard for management of young dairy animals, once the farm operation is certified as organic. The following language is suggested:

§ 205.236 Origin of livestock.

2) *Dairy animals - conversion of herds*. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to

the production of the milk or milk products that are to be sold, labeled, or represented as organic, Except, That, crops and forage from land, included in the organic system plan of a dairy farm, that is in the third year of organic management may be consumed by the dairy animals of the farm during the 12-month period immediately prior to the sale of organic milk and milk products.

- (3) Dairy animals - replacement stock. Once an operation has been certified for organic dairy production, all dairy animals, including all young stock whether subsequently born on or brought onto the operation, shall be under organic management from the last third of gestation.

This issue has been debated and was subject of NOSB recommendations since October of 2002, and has received a great deal of public comment. If the agency does not address this needed clarification at this time, we urge prompt action on a new Proposed Rule to include this change. An Advanced Notice of Proposed Rule Making will cause unnecessary delay in remedying the unfair double standard that this proposed rule fails to correct.

Revision is Needed for §205.600(b), Criteria for Synthetic Substances

The Court ruled in the Harvey case that regulations establishing criteria for review synthetic substances found at §205.600(b) were contrary to the plain language of the OFPA. (396 F.3d at 40). The NOP states that in November 2005 Congress amended the OFPA by “permitting the addition of synthetic substances appearing on the National List for use in products labeled “organic.” (71 Fed. Reg 24821). The USDA now states that this alters the need for the NOP to remove the regulations at §205.600(b). However, the current language inconsistently applies these criteria to synthetic “processing aids and adjuvants”, substances not specifically referenced in the Nov. 2005 OFPA amendment. It is extremely important to retain the stringent review criteria for use during the evaluation of any synthetic substance proposed for inclusion on the National List. Therefore, please make a technical correction in §205.600(b) to be consistent with the agency’s interpretation of the Congressional amendment. The regulation should be amended as follows:

§205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

a) * * *

b) In addition to the criteria set forth in the Act, any synthetic substance used in handling as ~~a processing aid or adjuvant~~ will be evaluated against the following criteria:

1) * * *

This correction will be consistent with the current NOP policy for materials review, which applies these criteria to all synthetic substances petitioned for handling, and are referenced in checklist evaluations used by NOSB for that purpose.¹

¹ Evaluation Criteria For Substances Added To The National List,
<http://www.ams.usda.gov/nosb/meetingbooks/Oct2003/MaterialForms.pdf>

Revision Needed for § 205.605, Synthetic substances

In order to be consistent with the USDA interpretation of the Congressional amendments, §205.605 should undergo the following technical revision:

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

The following nonagricultural substances may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

This change will clarify that all substances, which **include** both ingredients and the ingredients considered to be “processing aids”², must appear on the National List in order to be used in foods labeled “organic” or “made with organic” ingredients.

Allowance of Other Synthetics

The NOP should also further clarify the status of synthetic substances in a consistent manner, by rescinding its “draft” policy allowing some synthetic substances, such as indirect food additives and FDA identified “food contact substances”, to be used in products labeled “organic” or “made with organic” without review by the National Organic Standards Board.^{3 4} This confusing policy has not been uniformly applied, and is not well-understood by certification agencies. The broad allowance of many synthetics that do remain in food under this FDA policy, is contrary to the Court order and OFPA principle expressed that agricultural products labeled as organic shall “have been produced and handled without the use of synthetic chemicals, except as otherwise provided in this title.” (7USC 65104(1)) The “draft” policy would also allow things such as the synthetic juice preservative dimethyl dicarbonate to be used in organic products without NOSB review, and preservatives used in packaging in conflict with OFPA.⁵ As recently shown at the

² See FDA regulations at 21 CFR Sec. 170.3 Definitions (e)(1) Food additives, 170.3 (g) substances, 170.3(m) food; 21 CFR Part 101--Food Labeling, Sec. 101.4 Food; designation of ingredients, also Sec. 101.100 Food; exemptions from labeling (a) (3) (ii) processing aids. FDA considers processing aids to be a subset of food additives, which are considered food ingredients.

³ USDA/NOP, “Synthetic Substances Subject to Review and Recommendation by the National Organic Standards Board When Such Substances Are Used as Ingredients in Processed Food Products” available at <http://www.ams.usda.gov/nop/NOP/PolicyStatements/SyntheticSubstances.html>

⁴ The NOP has stated that the current Food Contact Substance policy is not final and “is part of an ongoing deliberation about how the Act and Rule operate.” Brief of Appellee at 23-24, n. 11, *Harvey v. Veneman*, 396 F.3d 28 (1st Cir. 2005) (No. 04-1379).

⁵ See detailed analysis of this policy presented to the NOSB by Organic Materials Review Institute in May 2003, available at <http://www.ams.usda.gov/nosb/PublicComments/NOPSynthSubstOMRI030703.pdf>, and <http://www.ams.usda.gov/nosb/PublicComments/AppendicesNOPSynthSubsOMRI030703.pdf>

April 2006 NOSB meeting, consumer expectation is that organic products are not highly processed with chemicals, additives, or preservatives.⁶

Proposed Amendments to § 205.606

This section of the rule has been revised accurately to reflect the Court order that 205.606 be clarified to indicate that this is the complete list of non-organic agricultural substances allowed in organic products. However, another technical correction is required to remove existing language that states these restrictions are also applicable to those products labeled as “made with organic (specified ingredients or food group(s)).” Products in the “made with organic” category may contain up to 30% by weight of any non-organic agricultural ingredients, not only those on the National List. (205.301(c)) This section of the rule is being clarified in response to the Court order to accurately reflect its application and scope, therefore the inaccurate references to the “made with organic” labeling category should be removed.

Commercial Availability

The Congressional amendment to OFPA gave the Secretary the ability to “develop emergency procedures for designating agricultural products that are commercially unavailable in organic form for placement on the National List for a period of time not to exceed 12 months.” These agricultural products can make up only “less than 5%” of the ingredients in processed product labeled as “organic.” While amending §205.606, the agency has remained silent on its implementation of the amendments’ “emergency procedures.” The agency does have emergency provisions available already, under §205.290, which could be applied to handling provisions at §205.270- 205.272 in case of natural disaster. The provisions of §205.290 have not yet been invoked to date, so need for this is not apparent at this time.

The use of non-organic ingredients in organic processed foods fundamentally impacts the meaning of the organic label, and any process or criteria for expedited establishment of commercial un-availability should be subject to notice and comment rulemaking.

Respectfully submitted,

Emily Brown Rosen
Organic Research Associates

Lynn S. Coody
Organic Agsystems Consulting

⁶ see presentations of the Natural Marketing Institute available at <http://www.ams.usda.gov/nop/PublicComments/DairyPastureSymposium/MaryEllenMolyneux.pdf>, and Whole Foods Inc. at <http://www.ams.usda.gov/nop/PublicComments/DairyPastureSymposium/MargaretWittenbergPresentation>